EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO. 2187

THIS DOCUMENT RELATES TO: ALL WAVE 1 AND 2 CASES IN BARD MDL: 2187 AS WELL AS THE FOLLOWING SPECIFIC CAUSES OF ACTION

LYNDA BARNER AND RODNEY BARNER, **Plaintiffs,** **v.** **C. R. BARD, INC.,** **Defendant.**	**Civil Action File No.: 2:11-cv-00055**
PATRICIA BOSSE, **Plaintiff,** **v.** **C. R. BARD, INC.,** **Defendant.**	**Civil Action File No.: 2:13-cv-02349**
PATRICIA GOLD and ROBERT GOLD, **Plaintiffs,** **v.** **C.R. BARD, INC.,** **Defendant.**	**Civil Action File No.: 2:14-CV-11565**

FAYE TINNEN and JACK TINNEN,	)	
	)	
Plaintiffs,	)	
	)	**Civil Action**
v.	)	**File No.: 2:11-cv-00814**
	)	
C. R. BARD, INC.,	)	
	)	
Defendant.	)	
	)	

RULE 26 EXPERT REPORT OF ALAN GARELY, M.D.

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

I. QUALIFICATIONS

I received my BA in Liberal Arts from Hampshire College in Amherst, Massachusetts in 1984 and graduated with an MD from Saint Georges University School of Medicine in Grenada, WI, in 1989. I did my internship and residency in Obstetrics and Gynecology between 1989 and 1993 at the Saint Vincent‟s Hospital and Medical Center in New York City. I did my first year of fellowship in Urogynecology and Pelvic Reconstructive Surgery at the Sinai Hospital/University of Connecticut from July 1993-June 1994. My second year of fellowship was from July 1994-June 1995 at the Louisiana State University (LSU) Medical Center of New Orleans.

I remained at LSU as an Assistant Professor of Obstetrics and Gynecology until October 1997. From October 1997 until May 2002 I was the Associate Director of Urogynecology and Pelvic Reconstructive Surgery at North Shore University Hospital and an Assistant Professor of Obstetrics and Gynecology at New York University School of Medicine. After leaving North Shore, I became the Vice-Chair of Obstetrics and Gynecology, Chief of Gynecology, and Director of Urogynecology and Pelvic Reconstructive Surgery at Winthrop University Hospital

on Long Island and an Associate Professor of Obstetrics and Gynecology at the State University of New York, Stony Brook. From September 2009 until June 2012, I was the Director of Urogynecology and Pelvic Reconstructive Surgery at the Icahn School of Medicine at Mount Sinai, in New York. Since 2009 until the present, I am also an Associate Professor of Obstetrics, Gynecology, and Reproductive Medicine, at Mount Sinai. Since July 2012, I have been the Chair of Obstetrics and Gynecology and Director of Urogynecology and Pelvic Reconstructive Surgery at the South Nassau Communities Hospital in Oceanside, New York. I remain active in the accredited fellowship program in Female Pelvic Medicine and Reconstructive Surgery at Mount Sinai and do formal teaching with medical students, resident, and fellows, every week. I have trained 17 fellows in Female Medicine and Reconstructive Surgery.

I received my Board Certification in Obstetrics and Gynecology in 1997 and my Board Certification in Female Pelvic Medicine and Reconstructive Surgery in 2013 (first time it was given). Both certifications are active until December 2014.

I am a member of the American Urogynecologic Society (AUGS) and served on its Board of Directors from 2006-2009 and was the Director of the AUGS Government Relations Committee during that time. From 2000-2003 I served on the AUGS Public Relations Committee. I am currently the AUGS representative to the American College of Surgeons (ACS), and am in my second term on the ACS Obstetrics and Gynecology Advisory Board. I am a fellow of both the American College of Obstetricians and Gynecologists and the American College of Surgeons. I have been an Oral Board Examiner for the American Board of Obstetrics and Gynecology since 2010.

I have been a Journal Reviewer for Obstetrics and Gynecology, International Urogynecology Journal and Pelvic Floor Dysfunction, Ob-Gyn Management, Nature (Clinical

Practice Urology), American Journal of Managed Care, Journal of Reproductive Medicine, Expert Opinion on Emerging Drugs, Journal of the American College of Surgeons, and the Journal of Female Pelvic Medicine and Reconstructive Surgery.

I was given the Association of Professors of Gynecology and Obstetrics (APGO) "Excellence in Training" award in 2007. I was the AUGS-ACS Health Policy Scholar in 2007 and was a Berlex Foundation Scholar in 1997.

I have written 17 peer-reviewed publications with three of them specific to pelvic floor mesh. I am the first author of the "Expert Opinion Series on the Surgical Treatment of Stress Incontinence" which will be published in the December issue of Obstetrics and Gynecology (The Green Journal). I have written 4 book chapters on pelvic floor disorders and pelvic fistula. I have presented 38 papers and have given 88 lectures both nationally and internationally.

Publications

Mesh erosion following abdominal sacral colpopexy in the absence and presence of the cervical stump.
Ginath S, Garely AD, Condrea A, Vardy MD.
Int Urogynecol J. 2013 Jan;24(1):113-8. doi: 10.1007/s00192-012-1845-5. Epub 2012 Jun 21.
PMID: 22717784 [PubMed - indexed for MEDLINE]
Related citations

Magnetic resonance imaging of abdominal versus vaginal prolapse surgery with mesh.
Ginath S, Garely AD, Luchs JS, Shahryarinejad A, Olivera CK, Zhou S, Ascher-Walsh CJ, Condrea A, Brodman ML, Vardy MD.
Int Urogynecol J. 2012 Nov;23(11):1569-76. doi: 10.1007/s00192-012-1783-2. Epub 2012 Apr 28.
PMID: 22543549 [PubMed - indexed for MEDLINE]
Related citations

MRI pelvic landmark angles in the assessment of apical pelvic organ prolapse.
Ginath S, **Garely A**, Luchs JS, Shahryarinejad A, Olivera C, Zhou S, Ascher-Walsh C, Condrea A, Brodman M, Vardy M.
Arch Gynecol Obstet. 2011 Aug;284(2):365-70. doi: 10.1007/s00404-010-1648-1. Epub 2010 Aug 21.
PMID: 20730542 [PubMed - indexed for MEDLINE]

Recognition of occult bladder injury during the tension-free vaginal tape procedure.
Abbas Shobeiri S, Garely AD, Chesson RR, Nolan TE.
Obstet Gynecol. 2002 Jun;99(6):1067-72.
PMID: 12052601 [PubMed - indexed for MEDLINE]
Related citations

Paravaginal repair of lateral vaginal wall defects by fixation to the ischial periosteum and obturator membrane.
Scotti RJ, Garely AD, Greston WM, Flora RF, Olson TR.
Am J Obstet Gynecol. 1998 Dec;179(6 Pt 1):1436-45.
PMID: 9855578 [PubMed - indexed for MEDLINE]

Surgical landmarks of the ureter in the cadaveric female pelvis.
Barksdale PA, Brody SP, Garely AD, Elkins TE, Nolan TE, Gasser RF.
Clin Anat. 1997;10(5):324-7.
PMID: 9283730 [PubMed - indexed for MEDLINE]

Book Chapters

Garely AD, Krieger BR, Ky AJ. Rectal Prolapse, Current surgical Therapy, 2014, 11th Edition, Eds. JL Cameron and AM Cameron

Garely AD, Olivera C. Minimally invasive surgery for urinary incontinence. Chapter 12, Operative Gynecologic Laparoscopy: Principles and Techniques, 2008, Eds. F Nezhat and C Nezhat

Garely AD, Kaufman L. Transabdominal procedures for the treatment of stress urinary incontinence. Chapter 8, Female Pelvic Health, 2002, Eds. Carlin and FC Leong

Elkins TE, **Garely AD**. Repair of vesicovaginal, urethrovaginal and ureterovaginal fistulas. Section XV. Gynecologic Surgery. 1995. Eds. T. Stoval and W. Mann

My first experience with mesh used to treat pelvic floor defects was in 1998, when I trained on the Gynecare TVT sling, at the Karolinska Institutet, in Sweden. After returning from Sweden, I did one of the first TVT operations in the United States. I was an active preceptor and proctor on the procedure until 2002. From 2003-2004, I was involved in the teaching and preceptoring of the IVS Tunneler, used to treat apical vaginal prolapse. After 15 cases with this device, I abandoned its use secondary to a high rate of mesh erosions and failures. Over the past 15 years, I have done consulting work for Gynecare, US Surgical/Tyco, Covidien, Caldera,

AMS, and Bard. Specific to Bard, I spent one day consulting on their pelvic floor products in 2008. I have never used any transvaginal mesh products for the treatment of vaginal prolapse except for the IVS Tunneler. I worked with AMS to develop the Interpro Y mesh and with Gynecare to make changes in the first generation of the TVT sling.

I have reviewed numerous Instructions for Use (IFU) for a variety of medical products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the devices.

I have extensive clinical experience with IFUs and instructing patients about the adverse events and risks contained in IFUs. I have gained expertise in IFUs through my extensive clinical experience reviewing IFUs and consenting patients regarding IFUs. I have been a practicing pelvic reconstructive surgeon and educator for 19 years. I was an active participant in the first wave of vaginal mesh surgeons. I taught hundreds of surgeons how to implant slings and Transvaginal mesh products. After patients started having post implant complications, because of my extensive experience as an implanting surgeon, I became a referral resource for mesh explanting. My experience with IFU's comes from evaluation and discussions with the device manufacturers themselves.

I have significant experience with pelvic repair surgery.

I have personally examined, diagnosed and treated thousands of patients with mesh complications. I have performed about 6,000 pelvic organ prolapse surgeries.

I am familiar with the Avaulta Solo and Avaulta Plus kits specifically, as opposed to just mesh products generally. I have surgically revised or removed over 200 prolapse meshes. I am a regional referral center for pelvic mesh complications in the New York tri-state area. I have taught and lectured about mesh complications on a regular basis.

I have personally removed Avaulta Plus and/or Solo mesh. I know this because I have undergone a deposition as an explanting surgeon on one of my own patients who had an Avaulta Plus, and I have received patient operative notes and attorney letters informing about the mesh that was removed.

I have received and reviewed Bard Avaulta Solo/Plus videos.

I have been to many professional conferences where the Avaulta Solo and Plus were both presented and discussed.

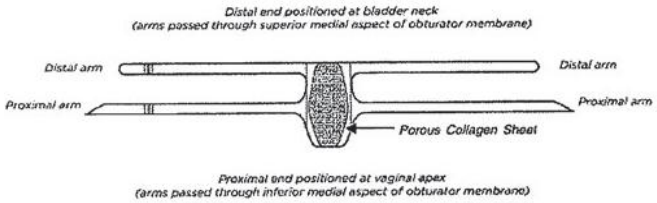
METHOD OF IMPLANTATION OF AVAULTA PLUS AND AVAULTA SOLO

The Avaulta Plus and Avaulta Solo Pelvic Organ Prolapse repair systems require transvaginal implantation of polypropylene mesh (Solo) or a porcine collagen layer affixed to polypropylene mesh (Plus) using specially designed trocars. These products are comprised of a central mesh portion and four flat mesh arms, which are supposed to anchor the mesh in the obturator internus and levator ani muscles and other tissue. The arms are passed proximally and distally through the obturator foramen, near the ischial spine proximally, and near the junction of the superior and inferior pubic rami distally.

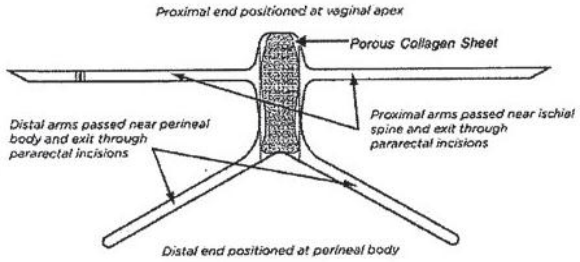
The below images depict the Avaulta Plus and Avaulta Solo products, both the anterior and posterior versions:

AVAULTA PLUS

Anterior

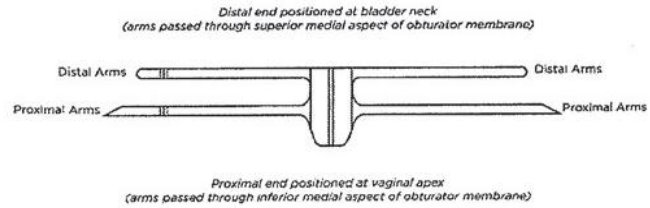


Posterior

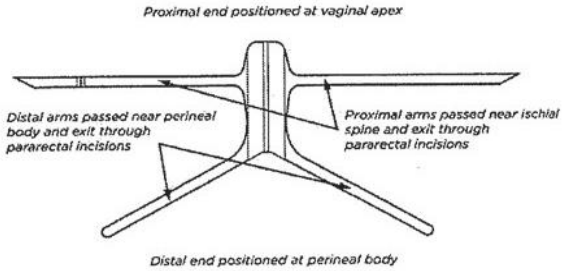


AVAULTA SOLO

Anterior



Posterior



The products are implanted by blindly passing trocars inward through the perineal skin, obturator foramen, obturator internus, and/or levator ani, out through a mid-vaginal incision, then by attaching the mesh arms to a snare device in the trocar, and pulling the trocar with each arm of the mesh outward into place, thereby placing the mid portion of the mesh either between the bladder and anterior vaginal wall (anterior Avaulta) or between the rectum and the posterior vaginal wall (posterior Avaulta). The anterior Avaulta products require four trocar passages through four separate incisions. The posterior Avaulta products also require four trocar passages, but there are only two incisions, so that the proximal and distal arms on one side exit through one skin incision site and actually overlap one another as they approach the skin. As the Avaulta mesh arms are being pulled into place, the tension on them causes deformation and

curling of the arms, altering the shape of the arms and the size and shape of the pores of the arms. The polypropylene mesh arms are intended to scar into place at the muscle attachment points for each arm, with two arms in the left pelvic sidewall muscles and the other two arms in the right pelvic sidewall muscles. In this way, the central portion of the Avaulta mesh is intended to support the anterior and/or posterior walls of the vagina and correct anterior and/or posterior prolapse.[1]

III. EXPERT OPINIONS

All of my opinions in this report I hold to a reasonable degree of medical certainty.

A. Bard failed to adequately warn physicians and patients about known problems with the Avaulta Plus and Avaulta Solo products.

In November 2008, I went to the Bard training facility in Covington, GA. The purpose of the meeting was to have discussions regarding Bard's Align and Avaulta products and procedural improvements (i.e. approaches to standardize best practices: incision, dissection, operative time and post-op care). The meeting also included discussions regarding Bard's MIS to obtain input on product design, and procedural steps. Prior to this meeting I had used the Bard Pelvicol porcine dermal graft in both anterior and posterior vaginal wall repairs. I also had experience in removing these grafts after some of them developed complications.

As an active explanting surgeon for this particular transvaginal mesh, I have reviewed and am familiar with the Instructions for Use (IFU), Physician Training materials, and sales and marketing materials prepared by Bard for the Avaulta Plus and Avaulta Solo products. I have also reviewed the IFUs for many other medical products that I have implanted and explanted in

[1] Avaulta Plus and Solo Instructor"s Module; Bard Avaulta Plus and Solo Procedural DVD.

patients during the 19 years I have been practicing urogynecology and pelvic reconstructive surgery.

The Instructions for Use booklet (IFU) is one medium that physicians reasonably rely upon to make informed decisions about whether and how to use a medical device. The contents of the IFU should assist the physician in his or her risk-benefit analysis that is employed when determining whether to recommend a particular product as a surgical option to a patient. I have read the IFUs for the Avaulta Solo and Plus kits.

Physicians also regularly and reasonably rely on information provided by medical device manufacturers in other forms besides the IFU, such as patient brochures, physician training materials, and direct communications with sales and marketing personnel and other company employees. In order to make an informed decision as to whether to use a particular product in a given patient, a reasonable physician would expect a medical device seller to provide all pertinent information known to the company that could impact a reasonable physician"s decision to use that product. Failure to provide physicians with relevant information bearing on the potential safety of a product that is known to the manufacturer prevents physicians from making informed decisions about whether to utilize the product. This failure also prevents physicians from properly counseling patients in considering whether to consent to permanent implantation of the medical device.

Additionally, in making an informed decision of whether or not to use a medical implant, the physician must be warned not only of the potential adverse events that may be associated with the product, but also the frequency, severity, duration and potential permanence of those adverse events. If a medical device manufacturer knows that the design features of its product cause or increase the risk of a complication, or present a risk unique to that product"s design,

then it would be misleading and inadequate for that manufacturer to represent to users of the device that the risks associated with that product "are those typically associated with surgically implantable materials," as is stated in the IFUs for the Avaulta Plus and Avaulta Solo. Likewise, if a manufacturer knows that a complication can be chronic, severe or permanent, it should provide that information to those using its products.

Bard failed to warn physicians and patients about the following. In my opinion, the omission of instructions or warning as set forth below rendered the Avaulta Plus and Solo devices not reasonably safe.

1. Bard knew that the specific polypropylene grade that was used to make the Avaulta mesh, Marlex HGX-030-01, was "not approved for medical implants" [2] and that the polypropylene material used to manufacture the mesh contained a "MEDICAL APPLICATION CAUTION" in the Material Safety Data Sheet ("MSDS") which stated "Do not use this [ ] material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues."[3] A Phillips Sumika Marlex HGX-030-01 information sheet listed the following as suggested uses for the particular polypropylene grade: Woven industrial fabric and bags, rope and cordage, woven carpet backing, and geotextile fabrics.[4] The MSDS for the polypropylene material also warned of "Incompatibility With Other Materials," stating that the material "May react with oxygen and strong oxidizing agents, such as chlorates, nitrates, peroxides, etc."[3]

[2] Davol Project Zebra Due Diligence Report, MPPE – 05710444.

[3] Marlex HGX-030-01 Material Safety Data Sheet, AVA2E0397833-41.

[4] AVA2E8761578; AVA2E0613193.

The manufacturer of the polypropylene material used to manufacture the Avaulta Plus and Avaulta Solo products, Phillips Sumika, provided a "Technical Service Memorandum" (TSM), which warned that the material "can be attacked by some strong mineral acids, halogens and oxygens," that "[t]he effect of strong oxidizing agents is an attack on the polymer chain" resulting in eventual degradation and embrittlement of the polypropylene.

2. According to Bard, the largest pore sizes of the Avaulta Plus and Avaulta Solo mesh averaged 1.0 mm in the arms and 1.3 mm in the central portion, yet Bard"s internal documents, as well as one of Bard"s chief medical advisors, Dr. James Ross, and Bard"s Director of Advanced Surgical Concepts, Bobby Orr, recommended that polypropylene mesh should have pores sizes that were 2 mm or more in order to promote tissue ingrowth and reduce shrinkage and contracture of the mesh within scar tissue so as to reduce scar plate formation and resulting complications, including dyspareunia, pain, erosion, extrusion, dehiscence, and abscess.

Bard"s measurements of the Avaulta mesh pores showed many pore sizes below 1 mm.[5] Most were below the pore size represented by Bard and far below the minimum pore size recommended by Bard"s consultants and scientists, as recognized by scientific literature.[6]

3. The mesh in the arms of both the Avaulta Plus and Solo products had a density of 64.5 g/m². Bard recognized a maximum safe density of 35 g/m^2 , relying on scientific literature.[7]

[5] AVA20096615 (Mesh Testing Characterization).

[6] AVA2E0074398 (9/2/08 Mesh Development Proposal memo); AVA2E7593856 (5/21/09 "Current Status of Mesh to BUD Biomaterials Expertise" memo); AVA2E0759628 (11/6/09 "Biomaterials Strategy Overview for Pelvic Health Products" memo); AVA2E0864856 (4/26/11 Bard V.P. for Regulatory and Clinical Affairs Email acknowledging mesh design flaws); (J. Ross depo. pp. 64:23-66:17 (less than 2 mm pore size causes scar bridging and is "not a good thing."); (R. Orr depo., pp. 117:3-13 (published data establishing appropriate pore size of greater than 2 mm was published and available before 2008)); Cobb W et al. "The Argument for Lightweight Polypropylene Mesh in Hernia Repair," Surgical Innovation, Vol. 12, No.1 (March), 2005: pp. 63-69; Klosterhalfen B et al. "The Lightweight and Large Porous Mesh Concept for Hernia Repair," Expert Rev. Med. Devices 2(1), 2005.

[7] AVA2E0074398 (9/2/08 Mesh Development Proposal memo), p. 4399 ("the mesh should be less than 35 g/m^2."); *See also*, AVA2E0864856 (4/26/11 Bard V.P. for Regulatory and Clinical Affairs Email acknowledging mesh

4. Bard knew and recognized, based in part on published literature that pre-dated the launch of the Avaulta Plus and Solo products, that "design of a more light weight, open pore mesh is needed" because mesh products sold for pelvic repair were, according to Bard"s own internal memoranda:

a. "[A]ssociated with reoccurrence and adverse events."

b. "[A]ssociated with various morbidities including dyspareunia, pain, erosion, extrusion, dehiscence, and abscess, to name a few."

c. "Over engineered with regard to strength for the biologic requirement" and,

d. "The pore size results in formation of a scar plate that is rigid and does not integrate well over time with the host tissue."[8]

5. Bard recognized that the contraction/shrinkage rate associated with mesh products was between 30% and 50%, and that this shrinkage was directly correlated to scar plate formation.[9] Bard"s own documents further acknowledge that "the postoperative scarification process significantly shrinks the tissue around the mesh, increasing the tension on the graft."[10]

6. Bard conducted only very short-term animal studies prior to marketing the Plus and Solo products to physicians. The studies did not demonstrate that the products could be safely implanted in humans, and the Bard scientist who was in charge of those studies testified that she could not conclude from those studies that the product could be safely used in humans.

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weight should be less than 35 g/m^2); AVA20020365 (Bard internal measurements for density of Avaulta Plus mesh arms); Kling U et al., "Functional and Morphological Evaluation of a Low-Weight, Monofilament Polypropylene Mesh for Hernia Repair," J Biomed Mater Res (Applied Biomater 63: 129-136, 2002).

[8] AVA2E0074398 (9/2/08 Mesh Development Proposal memo); AVA2E7593856 (5/21/09 "Current Status of Mesh to BUD Biomaterials Expertise" memo); AVA2E0759628 (11/6/09 "Biomaterials Strategy Overview for Pelvic Health Products" memo); AVA2E0864856 (4/26/11 Bard V.P. for Regulatory and Clinical Affairs Email acknowledging mesh design flaws).

[9] AVA2E0074398 (9/2/08 Mesh Development Proposal memo), p. 4399 ("The reported shrinkage for mesh is 30-50% []. This is directly correlated to scar plate formation.").

[10] AVA2E0094647 ("Persistent Delayed Healing" memo).

The short-term animal studies of the Avaulta Plus that were conducted by Bard prior to the market launch of these products actually showed adverse results, such as an enhanced foreign body reaction and chronic inflammation, and the results were questioned by Bard"s own Medical Director.[11]

7. Bard was aware that the addition of a porcine collagen sheet to the central portion of the Avaulta Plus product invoked a heightened inflammatory response, and created a heightened risk for delayed healing, granulation tissue, discharge, bleeding, erosion, extrusion and rejection.[12] A study by Bard conducted on the porcine sheet before the product was ever marketed showed that the material "will be surrounded by host tissue without significant ingrowth" and that "encapsulation is the likely outcome…."[13] Despite this knowledge, Bard represented to physicians that the Avaulta Plus would help tissue ingrowth, decrease erosions, decrease the inflammatory response, promote healing, and reduce complications and the need for repair surgeries.[14]

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[11] D. Ciavarella depo., p. 69:18-20 (Bard"s Medical Director testified that "[i]f you use a 90-day study to extrapolate a conclusion for longer than that, then that would not be, you know, good science."); J. Mercuri depo., pp. 197:11-20; 198:14-199:24; 200:6-201:4; 201:22-25; 203:25-207:20); AVA2E0072438 (7/25/06 Emory rat study showing chronic inflammation, encapsulation, and minimal ingrowth); J. Mercuri depo., pp. 207:19-20; 208:15-209:8; 210:2-211:5; AVA2E0160009 (Ga. Tech rat study showing numerous complications and morbidities with "hybrid" material)); J. Mercuri depo., pp. 190:3-191:10; AVA2E0072785 (Sheep study draft report with Dr. Ciaverella"s comments: "*It looked like a lot of scar tissue between the mesh and collagen*," "*I was surprised by the extent of the reaction*," and expressing other concerns about the report findings). Jennifer Mercuri, the bioengineer hired Bard to conduct that animal testing, testified that she did not conclude that the testing supported the safety of the product. (J. Mercuri depo. pp. 213:12-17; 214:14 – 215:14).

[12] AVA2E0094647-51 ("Persistent Delayed Healing" memo); AVA2E0799229-30 (Bard email from A. Bowyer to Dr. Krick ("With the Avaulta Plus there is a higher risk of delayed healing/extrusion/rejection etc because of the porcine.")); AVA2E1131047-50 (Bard email from Jon Conta to Dr. Bailey ("Very glad to hear you"re not seeing any exposures with the Solo. Your experience mimics others, and continues to confirm to us that the delayed healing is specific to the collagen on the Plus….")); AVA2E0072438 (7/25/06 Emory rat study demonstrating chronic inflammatory response, encapsulation, and minimal tissue ingrowth with porcine collagen patch).

[13] AVA2E0072438 (7/25/06 Emory rat study); *See also*, AVA2E0315741 (Status of ASC Group Projects excerpt), p. 5751 ("Preclinical Research Conclusions: Avaulta is completely encapsulated with minimal cellular infiltration.")

[14] AVA2E1239117 (Bard 7/6/07 marketing e-mail to hospital stating "*The Avaulta Plus has everything that the [*competing product*] has PLUS is also has a piece of Porcine Graft attached to it. The purpose of this tissue is to act*

8. The Avaulta kits did not include sheaths or cannulas over the arms. Bard knew that the mesh arms on the Avaulta Plus and Solo products would cause tissue damage as they were pulled through the smaller, rounded trocar channel, causing the mesh to saw through tissue.[15] Bard also knew that by pulling the mesh through a trocar tract smaller than the width of the flat mesh arms, and bringing the mesh through incisions in the skin that were smaller than the width of the arms, that the mesh would curl and deform instead of staying flat, tear a small trocar tunnel into a "cat eye-like" defect in the sidewall, ligaments, or pelvic floor, and that this sawing of tissue would lead to increased pain and poor outcomes.[16] The issue had been recognized long before the launch of Avaulta Plus and Solo kits. In an April 2006 review of the Avaulta Plus/Solo prototype, a Bard medical adviser, Dr. Jim Ross, stated: "[d]oes the small needle passage „cord" mesh (force it into round shape the size of needle passage) and inhibit ingrowth?"[17]

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as a barrier between the patient's mucosa and the mesh. This barrier has proven to prevent erosions and increase overall patient comfort."); AVA2E7142403 (Bard 5/22/07 marketing e-mail stating "*We have made an improvement to our original barrier system which will protect your patients against complications associated with permanent implants such as inflammation, infection, and erosions. This barrier system is 1 of a kind! This barrier protects synthetic mesh against the vaginal mucosa. The result of this is a near prevention of erosions into the vagina. Our barrier system now includes porcine dermis tissue which the body will see as a natural tissue to trick the body into reducing rejection of the synthetic material*….

[15] AVA2E0218343 (7/20/06 Bard Email stating "[doctors] *see tearing the arm through the tissue...as a major disadvantage* [of the Avaulta product].*We would need data to say that it does not cause injury to the tissue* [as compared with the arms on a competing device, which were covered by a protective sheath during insertion] *if we were going to say that protecting that tissue from the arms was not important*."); AVA2E1439452 (10/10/07 Bard Email addressing doctor's "arm sawing" concerns, stating doctor "*is not alone in his concerns*" and that "*[t]he onus is on us to prove that the passing of naked mesh arms does not cause any harm.*"); AVA2E0225785(10/7/08 Bard internal memo recognizing need to "Reduce/eliminate sawing action of arms on pull through"); AVA2E5506346 (March 30, 2009 Bard internal memo discussing presentation by Bard expert, Vincent Lucente, that doctors "should never use a kit that did not have some form of sheathing/canular system for passing the arms…because of the sawing of tissue you would be doing pulling the mesh through and around the fulcrum, and that it could lead to increased pain, and poor outcomes.").

[16] M. Johnson email, AVA2E0225785; J. Young email, AVA2E5506349-52.

[17] AVA20099652

9. The use of trocars inserted blindly into muscle and other tissue created the unnecessary risk of nerve damage and tissue injury.[18]

10. It is almost impossible and extremely difficult to remove the Avaulta Solo and Plus mesh in its entirety once implanted, and even to remove parts of the mesh requires invasive surgery that few surgeons are qualified to properly perform. Bard failed to warn about this risk, and failed to provide any instruction or direction as to how to address complications, or what to do in the event mesh removal was necessary.

11. Bard knew before the Avaulta Plus and Solo products were released to the market:

a) that surgical mesh is a permanent implant that may make future surgical repair more challenging;

b) that a mesh procedure may put the patient at risk for requiring additional surgery for development of new complications;

c) that removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient"s quality of life; and,

d) that complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.[19]

All of the above is information that a reasonable physician would want to know and expect a product manufacturer to disclose so that he or she could make an informed decision on whether to implant the Avaulta Plus or Avaulta Solo products. For example, the IFUs do not

[18] AVA2E0114456 (March 2, 2009 Bard Product Opportunity Appraisal Form) ("The market for pelvic floor grafting systems is changing. New technologies have focused on minimizing the number of incisions required for implantation resulting in a better patient experience, ostensibly better pain scale results and lower ambulation times. Furthermore, these „single incision" technologies do not require the passage of trocars/needles potentially reducing the amount of tissue damage and the potential for laceration of adjacent neurological vascular structures.").

[19] 8/8/13 *Cisson* Trial Transcript (Laura Bigby testimony), pp. 84:19-25; 86:16-88:19; 90:22-91:11; 91:12-92:12 (acknowledging Bard"s knowledge of these issues with the Avaulta products).

mention that animal studies did not establish that the material could be used safely in women. There was never a mention of persistent delayed healing. There was no mention that the porcine collagen layer of the Avaulta Plus increases risks of erosion, extrusion and rejection. And there was no mention of the ischiorectal fossa inflammation and infections that were associated with the Avaulta Plus. Based on the information that Bard knew, Bard's representation in the IFU that the risks associated with these products include "those typically associated with surgically implantable materials" is inaccurate and misleading, as it understates and downplays the risks that are mentioned. Bard's failure to provide adequate and complete information to doctors prevented doctors and patients from reaching fully informed and educated decisions about whether to use the Avaulta products.

The IFU should have warned about the potential for the mesh to cord, buckle, "bunch" and rope, the potential for permanent pain as a result of such mesh, and the potential of multiple tedious and difficult surgeries in the event the mesh needed to be removed.

Having read and relied upon IFU's for urogynecologic medical devices used in the operating room over the past 19 years, it is my opinion that the type of information detailed above should be communicated to surgeons so that they can make safe treatment choices for their patients. Even if Bard did not have knowledge of the information at the time of the products' launch, once this information became available, the company should have made changes to the IFU and otherwise made reasonable efforts to ensure that physicians continue to have the information necessary to make informed and safe treatment decisions for patients. Bard changed or updated the IFUs for the Avaulta Plus and Avaulta Solo but never provided any of the information set forth above. If physicians are not fully and timely informed of all of the information known to the manufacturer bearing on the safety and efficacy of the product, they

cannot be expected to perform an adequate risk-benefit analysis or obtain adequate informed consent from their patients.

A medical device manufacturer which knows or believes that its devices cannot be safely used in any segment of its patient population must make reasonable efforts to warn and instruct its consumers regarding a restriction for those patients. According to the 2007 and 2008 IFUs, the only restricted patient populations for the Avaulta Plus and Solo products were patients who were pregnant or may become pregnant, may have a urinary tract infection or an active infection in the operative field, or patients in a period of growth. This implied to physicians that the use of the Avaulta devices in other patients, such as smokers, diabetics, steroid uses, fibromyalgia patients or patients with pre-existing pelvic pain, was medically justified. If Bard knew or believed that there may be risks specifically associated with the use of its Avaulta products in any given category of patients, it was obligated to so advise the physician users of the products. In addition, none of the Avaulta IFUs contain any discussion of long-term sequelae of complications such as multiple surgeries.

The Avaulta IFUs and implantation videos were confusing and misleading in their description of the insertion technique for the trocars and the depiction of the arms being pulled through the tissues and out to the skin.

In the anterior Avaulta cadaver video, as Dr. Ross is pulling the arms through the tissues, the arm is seen to come out through the skin in a “C” shaped configuration, not flat. In contrast, the animation video for the anterior Avaulta shows it exiting the skin in a perfectly flat shape and all four arms are shown flat where they exit the skin the circular configuration is productive of tissue sawing and interference with tissue incorporation due to the curled deformation.

In the IFU description of the insertion technique for the Anterior Avaulta Plus from 2007 to 2011, the exit point of the trocar proximally is variously described the vaginal apex or the top of vaginal cuff. The vaginal apex may be located in various locations in relation to the ischial spine and is, therefore, a very vague description of where the trocar should exit into the pelvic cavity.

In the IFU description of the insertion technique for the Anterior Avaulta Solo from 2007 to 2011, the exit point of the trocar proximally is variously described as at the ischial spine or the vaginal cuff. There is no direction given as to where in relation to the ischial spine the trocar should exit. The vaginal cuff may be located in various locations in relation to the ischial spine. This is, therefore, a very vague description of where the trocar should exit into the pelvic cavity.

In the IFU description of the insertion techniques for the Posterior Avaulta Plus from 2007 to 2011, the exit point of the trocar proximally is variously described as 1 cm proximal to the ischial spine or at or just cephalad to the ischial spine. Cephalad to the ischial spine would place the exit location beyond the spine and in a dangerous place relative to the pudendal nerve. Alternatively, the exit point, at the physician"s discretion, can be through the sacrospinous ligament. There is no statement as to where in the ligament it should be placed. The placement of a 12 mm wide polypropylene mesh through this ligament would also be close to the pudendal and sciatic nerves which could be damaged during insertion by the cording of the arm or later by the chronic inflammatory reaction induced by the mesh.

In the IFU description of the insertion technique for the Anterior Avaulta Solo from 2007 to 2011, the exit point of the trocar proximally is described as at the vaginal apex. This is an imprecise location since the vaginal apex may be at varying distances from the ischial spine.

Also in the animation of the posterior Avaulta insertion technique, the mesh arms are seen exiting the skin in a perfectly flat configuration, whereas in the cadaver video they are exiting in a "C" shape.

The Avaulta IFUs were also deficient regarding their explanation of the suggested vaginal dissection technique. The IFUs instruct the surgeon to "dissect the vaginal mucosa away from the bladder" and to "dissect the vaginal mucosa away from the rectum" before placing the mesh. These statements are unclear, vague and confusing and are ineffective ways to communicate these important dissection steps of the Avaulta surgery.

The IFU should instruct the surgeon to mobilize the entire full thickness of the vaginal wall so that there is access to the vesicovaginal (anterior) or rectovaginal (posterior) space. Otherwise, the surgeon may believe that proper placement of the mesh does not require a "full thickness" dissection and he or she may incorrectly place the mesh below the epithelium and not behind the vaginal wall.

B. <u>The design of the Avaulta Plus and Avaulta Solo products is defective.</u>

The design of the Avaulta Plus and Avaulta Solo products is defective for the following reasons:

1. The Marlex HGX-030-01 polypropylene used in the manufacture of the Avaulta Plus and Avaulta Solo products is not medical grade.

2. Upon insertion, the flat mesh arms of the Avaulta Plus and Solo products are pulled into and through a rounded trocar tunnel that is significantly smaller than the width of the mesh, and are pulled through tissue, including muscles and possibly the sacrospinous ligament, then exit the body through surgical wounds in the skin that are much smaller than the width of mesh. The four uncovered mesh arms of the Avaulta products tear through tissues upon and

during insertion, creating a sawing effect, and thereby causing tissue damage, pain and enhanced inflammation. [20]

3. The trocar-based insertion of non-sheath protected mesh arms through smaller, rounded trocar holes prevents the mesh arms from remaining flat, and inevitably causes them to deform, fold, curl and/or roll, [21] which results in or contributes to excessive scarification and contraction of the arms. In removing Avaulta mesh, I have observed that the mesh has become hard and brittle, and I have observed banding of the arms and bunching of the central mesh piece as a result of this scarification.

4. The density of the arms of the Avaulta mesh (64.5 g/ m^2) is almost twice the density that Bard recognized as the maximum safe density (35 g/ m^2) and increases the foreign body reaction to the mesh arms, which causes or contributes to a thicker and less compliant scar plate (i.e., a mechanical mismatch between the mesh and the tissue in which it is implanted).

5. In the hands of many gynecological and urological surgeons, the blind passage of the metal trocars done during the implantation is unreasonably dangerous and presents the unnecessary risk of tissue damage, vascular damage, nerve damage, and internal trauma that can be greatly reduced if not eliminated with other, safer designs.

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[20] AVA2E0218343 (7/20/06 Bard Email stating "*[doctors] see tearing the arm through the tissue...as a major disadvantage* [of the Avaulta product].*We would need data to say that it does not cause injury to the tissue* [as compared with the arms on a competing device, which were covered by a protective sheath during insertion] *if we were going to say that protecting that tissue from the arms was not important*."); AVA2E1439452 (10/10/07 Bard Email addressing doctor's "arm sawing" concerns, stating doctor "*is not alone in his concerns*" and that "*[t]he onus is on us to prove that the passing of naked mesh arms does not cause any harm.*"); AVA2E0225785 (10/7/08 Bard internal memo recognizing need to "Reduce/eliminate sawing action of arms on pull through"); AVA2E5506346 (March 30, 2009 Bard internal memo discussing presentation by Dr. Vincent Lucente that doctors "should never use a kit that did not have some form of sheathing/canular system for passing the arms…because of the sawing of tissue….

[21] Photographs of curled and deformed mesh arms being pulled through smaller, rounded trocar exit wounds taken from Bard Avaulta training videos.

6. As the four deformed mesh arms scar into tissue, they can pull asymmetrically on the central portion of the mesh. This results in the buckling, folding or wrinkling of the center mesh portion, which is intended to stay flat between the bladder and vagina and/or the rectum and the vagina. This, in turn, causes pain and can lead to erosion or extrusion of the mesh through the vaginal mucosa. The arms of the mesh pull on their anchoring points in the pelvic sidewall muscles (obturator and levator ani), tending to pull these anchoring points and the attached muscles toward the midline. This asymmetrical, non-uniform pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing and straining. Attempts at defecation or sexual penetration push on the mesh, aggravating the pulling on the arms, which in turn causes new or worsening pain. During many normal activities, pressure is placed on the mesh, which is transmitted to the attachments in the pelvic sidewall, also deforming and pulling on the muscle at the attachment points.[22]

As the central portion and arms of the Avaulta Solo and Plus scar in, the resulting shrinkage or contracture of the tissues surrounding the mesh can entrap nerves and result in severe, permanent and difficult-to-treat or untreatable pain as a result of the chronic inflammatory response and fibrosis.[23]

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[22] AVA2E0074398 (9/2/08 Mesh Development Proposal memo), p. 4399 ("The reported shrinkage for mesh is 30-50% []. This is directly correlated to scar plate formation."). AVA2E0094647 ("Persistent Delayed Healing" memo) ("[T]he postoperative scarification process *significantly* shrinks the tissue around the mesh, increasing the tension on the graft.") (Emphasis added).

[23] Smith T, et al., Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center. Female Pelvic Med Reconstr Surg 2013; 19:238-41; Klosterhalfen, et al., The Lightweight and Large Porous Mesh Concept for Hernia Repair. Expert Rev. Med. Devices 2(1) 2005; Castellanas ME et al., Pudendal Neuralgia After Posterior Vaginal Wall Repair with Mesh Kits: An Anatomical Study and Case Series. Journ Minimally Invasive Gynecol 19 (2012) S72.

7. The porcine collagen sheet affixed to the Avaulta Plus mesh causes an even greater inflammatory response than polypropylene, which is acknowledged by Bard‟s own internal documents.[24] This heightened inflammatory response can lead to delayed healing, discharge, bleeding, erosion, extrusion and rejection of the mesh. Bard‟s internal documents recognize that the porcine collagen element of the Avaulta Plus graft is the primary cause of persistent delayed healing, and they further acknowledge that Bard had previously seen persistent delayed healing associated with other collagen products (Pelvicol and Pelvisoft) which came onto the market in the early 2000s, years before the Avaulta Plus was ever marketed.[25]

8. The method for implantation of the Avaulta Plus and Avaulta Solo require the products to be implanted through a transvaginal approach. This means the mesh product goes through the vagina. The vagina is a clean-contaminated space, meaning that even after intensive antimicrobial preparation, there is normal vaginal flora that cannot be surgically cleansed from the operative field. The normal flora includes a diverse array of bacteria, including, but not limited to: Lactobacillus, Bacteroides, Peptococcus, Petostreptococcus, gardnerella, E. coli, Stretococcus, Staphylococcus, Mycoplasma, ureaplasma, Enterobacteriaceae, mobiluncus, Acinterobacter and Candida species. These bacteria can attach to the product, allowing the bacteria to be dragged into the patient‟s body, where the bacteria can grow. The presence of this bacteria can cause abscesses, fistulae, and infection. The porcine collagen sheet affixed to the

[24] AVA2E0094647-51 (“Persistent Delayed Healing” memo); AVA2E0799229-30 (Bard email from A. Bowyer to Dr. Krick (“With the Avaulta Plus there is a higher risk of delayed healing/extrusion/rejection etc because of the porcine.”)); AVA2E1131047-50 (Bard email from Jon Conta to Dr. Bailey (“Very glad to hear you‟re not seeing any exposures with the Solo. Your experience mimics others, and continues to confirm to us that the delayed healing is specific to the collagen on the Plus….”)); AVA2E0072438 (7/25/06 Emory rat study demonstrating chronic inflammatory response, encapsulation, and minimal tissue ingrowth with porcine collagen patch).

[25] AVA2E0094647-51 (“Persistent Delayed Healing” memo) (“By increasing the inflammatory response at the suture line, we believe the collagen element of the Avaulta Plus graft is the primary cause of PDH, as this is consistent with PDH seen previously in our Pelvicol and Pelvisoft products.”).

Avaulta Plus allows for greater bacterial attachment as there is more surface area to which the bacteria can attach, causing greater opportunity for abscesses, fistulae, and infection.

Several studies have shown bacterial colonization and infection of polypropylene mesh. Vollebregt, *et al*. published results from a study in which culture swabs of vaginal mesh were taken during surgical implantation. The authors concluded that "colonization of vaginally implanted mesh occurs frequently."[26]

9. Polypropylene mesh placed transvaginally is stiffer and less flexible than the native tissues in the vagina. The pelvic floor needs to be supple and flexible to perform its many functions. It must accommodate movement and forces associated with activities of daily living, such as coughing, walking, exercising, bladder filling and emptying, defecating, and sexual relations. Scar plate formation and mesh stiffness are incompatible with the natural functioning of the vagina. Literature on hernia mesh has reported that mesh can cause "considerable restriction of abdominal wall mobility" and "rigidity and discomfort, especially at the edge of the mesh are frequently reported complaints."[27] Since it was known from published literature that mesh can be or become rigid and restrictive, Bard should not have used this material in the vagina, which requires far greater flexibility than the abdomen. The fibrotic scar that encapsulates the Avaulta mesh due to the defective design features previously described causes even greater rigidity and less flexibility.[28]

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[26]Vollebregt, et. al., Bacterial colonization of collagen coated PP vaginal mesh: are additional intraoperative sterility procedures useful? Int. Urogynecol J Pelvic Floor Dysfun. 2009 Nov; 20(11): 1345-51.

[27]Junge, Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias suing mesh implants; Hernia 2001; 5: 113-118.

[28] AVA2E0864857 (4/26/11 Bard V.P. for Regulatory and Clinical Affairs Email) ("*It is our belief that until fairly recently (~2008) the available surgical mesh products used for POP repair may have been overengineered with regard to excess strength and minimal pore size when used in the pelvic floor. This shouldn't be surprising since the mesh products originally adopted for pelvic floor repair were designed (and cleared) for more general surgical*

10. It is extremely difficult and traumatic to attempt to remove all of the Avaulta mesh once it has been implanted. It is virtually impossible to remove all of an armed transvaginal mesh implant. There is no evidence that Bard ever considered what should be done if the mesh caused complications and the mesh needed to be removed, whether in whole or in part. An internal Bard PowerPoint recognizes that one of the "weaknesses" with its pelvic organ prolapse kits is "[t]repidation surrounding removal of kit system should something go wrong long-term."[29]

The inability to remove all of the mesh can cause long-lasting complications, including chronic pain. Surgeries to attempt to remove pieces of the mesh increase the presence of scar tissue, which can create or contribute to the patient's pelvic pain, dyspareunia and normal function of the pelvic area.

I have worked with medical device manufacturers in the development of pelvic repair mesh products.

In designing a pelvic repair mesh product intended to be sold and implanted by physicians like myself, a reasonable device manufacturer must consider and weigh all of the known risks versus the benefits of a particular design, as well as all information known to the manufacturer that may bear on the safety and efficacy of the design, including the gravity, severity, likelihood, and avoidability of the dangers associated with the design.

Particularly in light of Bard's knowledge about the risks inherent in the design of its products, which Bard's internal documents specifically recognize could be made safer by changing the products' design features, Bard's design of the Avaulta Plus and Solo products was

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uses such as hernia repair… These uses may represent environments under more stress with emphasis on structural repair compared to POP where functional compliance is paramount.").

[29] AVA20002052, p. 2063 (Bard PowerPoint recognizing "weaknesses" of pelvic organ prolapse kits).

unreasonably dangerous and defective. The Avaulta Plus and Avaulta Solo failed to perform as safely as a patient or physician would expect when implanted in the intended manner, and the probability of a serious complication developing was so high that the risk of using the product outweighed any potential benefit.

C. There are a number of safer feasible alternative designs than that utilized by Bard in the Avaulta Solo and Plus products.

Aside from the use of native tissue repairs, or non-surgical pelvic organ prolapse treatment like Kegel exercises and pessaries, there were several alternatives to the design of the Avaulta Plus and Solo products that would have been safer and just as effective if not more effective. Adoption of one or more of these alternatives would have reduced or avoided the foreseeable risks of harm that the Avaulta Solo and Plus devices posed. Failure to utilize one or more of these alternatives rendered the devices not reasonably safe and caused or substantially contributed to the complications and injuries that are listed in Section G of this report.

1. **Safer feasible materials to the polypropylene used by Bard in its Avaulta Solo and Plus products for the vaginal approach to prolapse repair.** Bard used a grade of polypropylene that was intended for use in woven industrial fabric, rope, and carpet backing, not medical devices, for the vaginal repair of prolapse.

In a patent application from 2007 for a biologic material intended for rectocele repair and other soft tissue support, Bard addressed the dangers associated with polypropylene mesh implants, stating: “Patches for use in surgical procedures can be made from synthetic mesh material, for example, polypropylene. Although easy to sterilize and inexpensive, synthetic material has a number of shortcomings. Perhaps most important, when synthetic mesh material is used as a support member, the roughness of the synthetic mesh may lead to abrasion of the

patient"s tissue, and that can [cause] infection and/or erosion of the tissue."[30] This would be especially true if the synthetic material was not medical grade.

2. **Elimination of four-arm, blind trocar implantation design of Avaulta Plus/Solo**. The four-arm, blind trocar-based implantation methodology is an inherent part of the design of the Avaulta Plus and Solo products, and it was inherently flawed. A safer implantation approach can be done with the abdominal sacrocolpopexy. I perform abdominal sacrocolpopexy (ASC) procedures using mesh. The ASC procedure is designed to address prolapse in the apical, anterior, and posterior pelvic floor. The ASC uses a "Y" shaped implant to lift the vaginal apex, anterior, and posterior walls to a position inside the pelvic cavity, by attaching the mesh to the anterior and posterior vaginal walls, and attaching the other end of the mesh to a ligament overlying the sacral promontory. Implants used in abdominal sacrocolpopexy are passed into position via an abdominal incision, and is not exposed to the native bacteria and other organisms in the vagina. Thus, the potential for microbial contamination of the ASC mesh is decreased.

Implants used as reinforcement in ASC are anchored in a vertical direction, and are not attached to the muscles in the pelvis. When abdominally placed mesh contracts during normal healing, this tends to result in a pulling up, or lengthening of the vagina, without the pain associated with pulling on skeletal muscle with the Avaulta Plus and Solo. Further, by placing the mesh abdominally instead of transvaginally, the risk for infection, excessive inflammatory response, delayed healing, erosion, and extrusion is reduced. For these reasons, the mesh placed for ASC behaves differently from, and cannot be compared with, transvaginally implanted Avaulta products. Products designed for ASC implantation are safer, feasible alternatives to transvaginal mesh like Avaulta Plus and Avaulta Solo mesh products.

[30] AVA2E6681921-1922 (Bard patent application for "Expandable Tissue Support Member and Method of Forming the Support Member").

The sacrocolpopexy abdominal implantation safer than the blind trocar passage utilized for the Avaulta Plus and Solo devices. The Alyte product designed and sold by Bard is implanted via sacrocolpopexy, and for reasons discussed above, thus presents far fewer risks than the four-arm, blind trocar passage utilized with the Avaulta Plus and Solo. While available only in Europe, it is possible that the Nuvia SI product, designed and marketed by Bard, is implanted via a single incision with a suturing device instead of trocars, and involves no blind trocar passes. The elimination of blind trocar passage reduces numerous risks associated with the Avaulta Plus and Solo products, and represents a safer feasible alternative product design.

3. **Larger pore, lighter weight mesh utilizing medical grade polypropylene without flat mesh arms**. If polypropylene mesh is ever utilized in a pelvic repair device, despite the availability of safer feasible alternative materials, then it should at a minimum be of medical grade material (as opposed to material expressly prohibited from being used in permanent human implantation, and which is known to be subject to oxidative degradation and embrittlement). The mesh should have large pores (at a minimum larger than 2 mm), should be lightweight (less than 35 g/m^2), should not be inserted blindly with metal trocars, and should not have flat mesh arms pulled through narrower, rounded trocar wounds.

Bard actually designed, developed and marketed products that incorporate these safer design features, including the Large Pore Soft Mesh hernia mesh, the Composix LP Hernia patch, repair device, as well as the Nuvia SI device for pelvic organ prolapse repair.

The Large Pore Soft Mesh hernia product, which was designed and marketed prior to 2006, has a smaller fiber diameter than that used in Avaulta Plus and Solo and has a significantly larger pore size (2.48 mm).[31]

[31] AVA2E7584130-138 (Bard Large Pore Soft Mesh Product Description)

The Composix L/P hernia mesh, which was designed and marketed before 2007, also has pores that are substantially larger than those of the Avaulta Plus and Solo products (2.8 mm).[32]

In addition, the Nuvia SI product is a larger pore mesh (3.165 mm x 4.278 mm) with tube-shaped arms,[33] which Bard knew was a safer design than the flat mesh arms of the Avaulta Plus and Solo products.[34]

Finally, mesh without arms, or sheet mesh, is safer than the use of the four-armed mesh design of the Avaulta Plus and Solo, for reasons previously discussed.

4. **No porcine dermis patch**. The addition of the porcine dermis patch to the Avaulta Plus only served to increase the risks associated with the already flawed polypropylene mesh itself, and provided no demonstrable benefit to patients.[35] A safer feasible design would be a larger pore mesh without arms that did not include an unreasonably dangerous porcine collagen patch.

[32] MPPE-03236234 (Bard Composix L/P Hernia Patch R&D Test Report – Physical Characteristics compared to Composix E/X).

[33] AVA2E3574654 (Nuvia Mesh Characterization Summary)

[34] An October 7, 2008 Bard Interoffice Memo proposed an alternative design using "rolled arms" or "laser edges" for the Avaulta Solo in order to "*[r]educe/eliminate sawing action of arms on pull through*." (AVA2E0225785). Similarly, an October 15, 2008 internal Bard design document proposes a new arm design for the Avaulta product, in part to *"address issues associated with excessive friction and/or the sawing action as seen during armpull through*." (AVA2E0023704). A January 2009 Research & Development Lab document indicates that Bard began studying the "*friction force through tissue*" of its mesh arm design versus a rolled and a tube-shaped arm design. (AVA20138954). Predictably, the flat mesh arms created a significantly higher friction force when pulled through tissue compared with the tube-shaped arm design. (*Id.*, pp. AVA20138955-AVA20138962).

[35]AVA2E0094647-51 ("Persistent Delayed Healing" memo);AVA2E0799229-30 (Bard email from A. Bowyer to Dr. Krick); AVA2E1131047-50 (Bard email from Jon Conta to Dr. Bailey); AVA2E0072438 (7/25/06 Emory rat study demonstrating chronic inflammatory response, encapsulation, and minimal tissue ingrowth with porcine collagen patch).

D. Bard's Argument That Polypropylene Has Been Used In Body For Decades

The mere fact that some other grades of polypropylene material have been used in other products that have been surgically implanted in the abdomen does not suggest, and certainly does not prove, that the use of the Marlex HGX-030-01 grade polypropylene in the form of the Avaulta Plus and Avaulta Solo products was appropriate for transvaginal implantation in pelvic organ prolapse surgery.

The fact that polypropylene mesh has been used for hernia repair in the abdomen does not establish or support its safety or efficacy for use in the female vagina.

Unlike the abdomen, the vagina is multiplanar and subject to multidirectional forces.

The vagina is composed of delicate, sensitive tissue.[36] As Bard acknowledged in 2011, "*[i]t is our belief that until fairly recently (~2008) the available surgical mesh products used for POP repair may have been overengineered with regard to excess strength and minimal pore size when used in the pelvic floor. This shouldn't be surprising since the mesh products originally adopted for pelvic floor repair were designed (and cleared) for more general surgical uses such as hernia repair… These uses may represent environments under more stress with emphasis on structural repair compared to POP where functional compliance is paramount*."[37]

Unlike the abdomen, the vagina is a "clean-contaminated" space, meaning that even after antimicrobial preparation, there is normal vaginal flora that is not cleansed from the operative field. The normal flora includes a diverse array of bacteria. These bacteria attach to the product and are carried into the spaces created by the Avaulta surgical approach (e.g., the ischiorectal

[36] In an internal memo dated May 26, 2009, Bard stated that based on cellular differences observed between vaginal versus abdominal tissue, "*changes in mechanical properties may also be unique*." (AVA2E7593756**)**.

[37] AVA2E0864857 (4/26/11 Bard V.P. for Regulatory and Clinical Affairs Email).

fossa in the Avaulta posterior devices), where the bacteria can grow. The presence of this bacteria can cause abscesses, fistulae, and infection.

5. In short, the environment of the vagina is not comparable with the abdomen, and to justify the use of transvaginal polypropylene mesh used in POP because sheet meshes that may have been made from a completely different grade of polypropylene were used in the abdomen is not scientifically or medically valid.

E. Clinical Trials Would Have Shown That Functional Outcomes Are Inferior With Transvaginally Placed Armed Mesh (TVM)

I have participated in numerous clinical trials and helped design many trials.

Patients are not more satisfied with armed mesh as compared to traditional repairs. And, in studies comparing the anatomical success of TVM with traditional repairs, the notion of what is a successful repair depends upon the different definitions of "success" given by the different authors.

When the definition of successful prolapse repair surgery includes both anatomic and functional outcomes, it is now clear that the risk of TVM surgery is greater than the benefit. "Transvaginal mesh has a higher re-operation rate than native tissue repair" due to the rate of surgeries for attempted repair of complications.[38]

It is also now clear that there is no functional or anatomic benefit for TVM in the posterior compartment.[39] TVM may offer improved anatomical outcomes for polypropylene mesh compared with anterior colporrhaphy. However, these outcomes do not translate into

[38] de Tayrac R et al., Complications of POP Surgery and Methods of Prevention, Int. Urogynecol. J. 2013; 24:1859-1872.

[39] Karram M, Maher C, Surgery for Posterior Wall Prolapse. Int. Urogynecol. J. 2013; 24(11): 1835-41.

improved functional outcomes or a lower reoperation rate for prolapse. The mesh group is also associated with increased morbidity, mesh extrusion, and higher reoperation rates. [40]

In a double-blind randomized trial comparing vaginal prolapse repair with and without mesh, there was no difference in anatomic benefit at three years; and there was a 15% mesh exposure rate after three months.[41]

To summarize, there is no good evidence supporting benefit in quality of life or relief of symptoms in any compartment with the use of TVM to treat pelvic organ prolapse, and many of the complications of TVM surgery are likely to be more frequent and more severe, unlike those seen with traditional prolapse repairs. In November, 2006, the French National Authority for Health (HAS) issued its report entitled "Evaluation of Mesh Implants Installed Through the Vaginal Approach in the Treatment of Genital Prolapse."[42] The evaluation was founded on a critical analysis of literature. A group of experts concluded that, given the variety of types of tested implants and treated indications, the amount of follow-up observation that rarely exceeded 2 years, the absence of comparative studies with alternative techniques in the majority of cases, and the uses of imprecise standards of evaluation, the data in the literature did not allow an effective evaluation of the anatomical and functional viability of implants in the treatment of prolapse through the vaginal approach. Some complications, several very serious, were identified. The analyzed literature did not allow an evaluation of their frequency. The report

[40] Maher C, Anterior Vaginal Compartment Surgery. Int. Urogynocol. J. 2013; 24:1291-1802; Ostergard D, Evidence-based Medicine for Polypropylene Mesh Use Compared with Native Tissue Repair. Urology 79: 12-15, 2012.

[41] Gutman et al., Three-Year Outcomes of Vaginal Mesh for Prolapse. Obstet Gynecol 2013; 122:770-7.

[42] French Nat'l Auth. for Health, Dept. of Evaluation of Medical and Surgical Procedures, Nov. 2006.

concluded that the use of mesh implants in genital prolapse surgeries by the vaginal route remained a matter of clinical research, and suggested a host of clinical trials.

Nevertheless, Bard did not agree to fund proposed clinical trials of the Avaulta Plus and Solo mesh kits and never conducted clinical studies before or after the Avaulta Plus and Solo kits were introduced to the market.[43] The peer-reviewed literature concerning Bard"s Avaulta mesh kits is sparse. The two best case series that were done concerning the predecessor to the Avaulta Plus and Solo kits, the Avaulta Biosynthetic product. In the anterior compartment, Cervigni et al. reported on 218 women and found a 76% objective anatomic success rate at three years, with a 12.3% mesh erosion rate and a vaginal stenosis rate of 7.7%. [44] Vollebregt *et al.* reported a randomized control trial comparing anterior colporrhaphy with the anterior Avaulta Biosynthetic for Stage 2 prolapse. At one year the objective anatomic success rate was much greater for the mesh group but there was no difference in awareness of prolapse or outcomes. There was a mesh exposure rate of 4% (hysterectomies were not done). Resolution of pre-operative dyspareunia occurred in 80% of the repair group compared with 20% in the mesh group. De novo dyspareunia was reported in 15% following mesh and 9% after native tissue repair. De novo rectocele occurred in 23% of the mesh group compared to 10% in the repair group. The authors concluded that despite the improved anatomical outcome in the mesh group, when using functional outcome as a definition of success, there was not enough evidence to support the use of TVM in primary anterior compartment prolapse surgery.[45]

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[43] Dan Delaney depo. pp. 29-30, 36, 139-140.

[44] Cervigni M, et al. Transvaginal Cystocele Repair with Polypropylene Mesh Using A Tension Free Technique. Int. Urogynecol. J. Pelvic Floor Dysfunct 2008; 19(4):489-96.

[45] Vollbregt A, et al. Primary Surgical Repair of Anterior Vaginal Prolapse: A randomized trial comparing anatomical and functional outcome between anterior colporrhaphy trocar-guided transobturator anterior mesh. 2011 BJOG 118(12): 1518-1527.

In 2010, Culligan, et al., published a retrospective study that purported to involve the Avaulta Solo, but actually appears to have involved both the Avaulta Solo and its predecessor, the Avaulta Biosynthetic.[46] The study found an erosion rate of 11.7% and a prolapse "cure" rate of 81% at follow-ups of at least one year.

A poster of Avaulta Plus presented by Rudnicki, et al., showed an increase in the objective prolapse "cure" rate after anterior repair but did not have a subjective cure rate and also showed a high erosion rate of 15% after 3 months.[47]

In 2013, a small prospective observational study that combined Avaulta Plus patients and Avaulta Biosynthetic patients with a median follow-up of 3 years claimed a good "cure" rate but had a 10% mesh extrusion rate.[48] There were 20 anterior and 20 posterior meshes implanted. One cannot tell how many were Avaulta Plus. The authors summarized the study by stating that "no conclusion can be made as to the advantages of this procedure."

In a 2013 retrospective study regarding the anterior Avaulta Plus, the authors reviewed literature regarding transvaginal mesh products in general and opined that the "high risk of altered sexual quality of life suggests that the use of mesh by vaginal route should be restricted to sexually inactive patients." The study had a mesh exposure rate of 15%. It concluded that the use of Avaulta Plus in the anterior compartment offered a high "success" rate with regard to prolapse repair "but with an important prevalence of vaginal mesh exposure." The porcine

[46] Culligan, et al. Evaluation of a transvaginal mesh delivery system for the correction of pelvic organ prolapse: Subjective and objective findings at least 1 year after surgery. AmJ Obstet Gynecol 2010; 203:506.e 1-6.

[47] Rudnicki, et al. The Use of Avaulta Plus For Anterior Repair, A Multicenter Randomized Prospective Controlled Study.

[48] Bondili, et al. Medium term effects of a monofilament polypropylene mesh for pelvic organ prolapse and sexual function symptoms. J Obstet Gynecol. 2012 Apr; 32(3): 285-290.

component of the Plus did not lessen mesh exposure, and the authors suggested further studies to evaluate the benefit of Plus‟s porcine sheet.[49]

I have read and studied and authored peer-reviewed urogynecological articles and participated in urogynecological clinical studies. Based upon the current literature regarding armed TVM kits and the few articles and abstracts regarding the Avaulta Solo and Plus products, upon what I have observed when I have removed Avaulta Plus and Solo mesh, and upon what I have learned from my review of Bard internal documents and testimony, it is my opinion that, had Bard conducted, sponsored or funded clinical trials before putting the products on the market in 2007, the results would have shown that the risks of implanting the Avaulta Plus and Solo mesh products far outweighed any perceived benefits, with unacceptable rates of mesh exposures, erosions, dyspareunia, persistent delayed healing, ischiorectal fossa abscesses and other infections, chronic pelvic pain, revisions and re-operations in an attempt to address these complications, and reoccurrences of prolapse following mesh removal surgeries.

It is also my opinion that the information available to Bard in the scientific literature concerning the potential for polypropylene degradation should have prompted Bard to conduct clinical studies to determine whether naturally occurring conditions in the pelvis and vagina could cause the polypropylene mesh to degrade and, if so, to establish what the clinical implications for patients would be.

F. Physician Training

Bard‟s physician training program for the Avaulta Plus and Solo products was inadequate, and resulted in Bard‟s “certification” of numerous physicians who were undertrained and who

[49] Thomin, et al. Genital Prolapse Repair with Avaulta Plus Mesh: Functional Results and Quality of Life. Prog Urol. 2013; 23(4): 270-5

lacked the experience, skills and expertise necessary to properly perform the implantation of these products.

Bard"s documents reflect that Bard did not consider physician training to be a priority, or even a necessity. For example, a Bard District Sales Manager instructed sales personnel to teach doctors how to perform implantation procedures, and encouraged sales personnel not to wait for physician training because "we don"t make commission on training," and only fall back on sending doctors to training as a "last resort" because "you [the sales rep] can lead them through these cases without waiting for training" and "there is no reason they can"t do these cases with your coaching."[50]

My personal experience with Bard as a high volume surgeon and national "thought leader" was that Bard was only interested in training as many physicians who indicated that they would use the Bard products, regardless of their previous surgical experience or ability. I personally raised this issue with Bard on numerous occasions and posited that their transvaginal mesh systems lacked data and would cause serious harm to patients. I can recall having conversations with my local Bard rep, who was more than happy to get his products into the hands of anyone willing to attend a training course.

G. General causation opinions

I have personally observed and treated patients who have been implanted with Avaulta Plus and Avaulta Solo products that experienced the following device-related complications:

1. Chronic pelvic pain;
2. Chronic inflammation of tissue surrounding mesh;

[50] AVA2E1442423 (McGowan/Studebaker email); M. Downey depo, pp. 401:7-15; 402:17-403:13; 406:15-407:4; 407:25-408:6.

3. Excessive scar plate formation, scar banding, and contracture of mesh arms, resulting in asymmetrical pulling on the central portion, causing pain;
4. Erosion of mesh into the bladder and rectum and exposure of mesh in the vagina;
5. Pudendal neuralgia;
6. Pelvic floor muscle spasm;
7. Direct trauma to organs and tissues and nerve injury and damage caused by the blind passage of trocars;
8. Direct trauma to tissue and nerves during implantation of the flat, uncovered mesh arms being pulled through smaller, round trocar tunnels;
9. Nerve damage or nerve entrapment as a result of mesh scarification and fibrotic bridging;
10. Dyspareunia;
11. Stress urinary incontinence and urge incontinence;
12. Urinary retention;
13. Constipation or fecal incontinence;
14. Deformed, wrinkled, folded, curled, roped, degraded and fragmented mesh upon removal;
15. Encapsulation of mesh (mesh covered in thick scar);
16. Vaginal shortening, tightening, stenosis and/or other deformation;
17. Infection as a result of the mesh, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses;

18. Fistulae;

19. Vaginal erosion and extrusion and visceral erosion; and

The published medical literature also reports these same types of complications with transvaginal pelvic organ prolapse repair implants.[51]

Based upon my education, training, experience and knowledge, and my familiarity with the published literature relating to this subject, it is my professional opinion to a reasonable degree of medical certainty that the injuries and complications that I have personally observed, diagnosed, and treated, with the Avaulta Plus and Avaulta Solo products are directly attributable to the defective design of these products as described previously.

H. Patient Reports

Based upon my work as a urogynecologist, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common mesh ‐ related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh ‐ related complications, I often determine the cause of the patient‟s complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

[51] Hansen, B., et al., *Long-Term Follow-up of Treatment for Synthetic Mesh Complications*, Female Pelvic Med & Reconstr Surg 2014, 20:126-130; Barski D, et al., *Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair.* Surg Technol Int. 2014, 24:217-24.; Shah, et. al., *Mesh complications in female pelvic floor repair surgery and their management: A systematic review*. Indian J Urol. 2012 Apr; 28(2):129-53; Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*, Obstet Gynecol 2010, 115:325-330; Morrisoe, S., et al., *The use of mesh in vaginal prolapse repair: do the benefits justify the risks?* Current Opinion in Urology 2010, 20:275-279; Blandon, et al., *Complications from vaginally placed mesh in pelvic reconstructive surgery*, Int Urogynecol J 2009, 20:523-31; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Int Urogyn J, 2009, 20:893-6.

RELEVANT MEDICAL HISTORY – LYNDA BARNER

-Visit with DR. Hockman **(2/18/08)** - Preop evaluation done and booked for Surgery on 2/25/09.

[1ST Surgery]
- Visit with Dr. Hockman **(2/25/08):** 1st surgery for cystocele, rectocele, incomplete uterovaginal prolapse. She underwent anterior-posterior colporrhaphy, vaginal colpopexy via sacrospinous ligament utilizing the total Avaulta Plus system. Uncomplicated surgery. She recovered well and was discharged home on POD 2.

-Visit with Dr. Hockman **3/26/08:** Patient presented with delayed wound healing. She had in office stitches placed to bring tissue together.

[2nd Surgery]
-Visit with Dr. Hockman **5/27/08:** Patient presented with complaints of dyspareunia and was taken to the operating room with mesh erosion and delayed healing. She underwent revision of prosthetic graft material via vaginal approach. She was discharged home on POD2.

[3rd Surgery]
-Visit with Dr. Hockman **8/15/08:** Patient underwent removal of prosthetic graft for complication related to genitourinary graft. There was a 2 cm long 0.5 cm wide area in the anterior vaginal wall, which exposed mesh and was excised. Uncomplicated surgery. She was discharged home on POD2.

-Visit with Susan Cooker, PA **2/19/09:** She presented for routine evaluation for menopause and hormone refill. She is not using Premarin cream anymore. She also c/o new vulvar rash that was itchy and burned. She was discharged with lotrosine, diflucan and premarin.

[4th surgery]
-Visit with Dr. Swift **5/18/09**: She presented to Dr. Swift‟s office w/ CC of vaginal pain and discharge. She is unable to have coitus with any exertion and has postvoid dribbling. She was taken to the OR w/ plan for repair of vaginal mesh erosion. However in the OR no mesh erosion was noted. She was diagnosed with postmenopausal bleeding and underwent cystoscopy, dilation and curettage w/ Dr. Swift. Normal hysteroscopy. Uncomplicated surgery. She was discharged home on POD2.

Visit with Dr. Swift **2/25/10**: She presented to Dr. Swift‟s office with c/o pain with coitus. She continues to have insertional dyspareunia since her cystocele and rectocele repair in 2008 despite vaginal estrogen therapy, followed by a 4-month treatment w/ vaginal dilator. At this point patient has failed conservative therapy of scar tissue and would like to proceed with surgery. On Bimanual exam there two areas in the left lateral sidewall and posterior fourchette that are exquisitely tender. There was an area on the right that had minimal tenderness. She was scheduled for surgery for 3/15/10.

[5th Surgery]

-Visit with Dr. Swift **3/15/10:** She underwent removal of vaginal mesh by DR. Swift. The posterior fourchette where patient reports extreme dyspareunia was examined. 2X2 cm tissue excised. Mesh protruding from the left lateral vaginal wall was removed.
Patient did well postop. She was discharged home on POD1.

-Visit with Dr. Kerry Hammond **5/2/14:** She was referred by Dr. Swift for fecal incontinence for the past 3-4 yrs. She reports 2-3x a week with gas, liquid and formed stools. Frequency worsened over the past 6 months. No nocturnal episodes. She wears pads for protection. Significant loss of sensation w/each surgery. She takes Imodium prn. She was thought to be not a surgical candidate. They recommend fiber supplementation, colonoscopy and kegels.

In determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Ms. Barner had Diabetes, hyperlipidemia, cystocele, rectocele and uterovaginal prolapse prior to the implantation of the vaginal mesh. She was diagnosed w/ Supraventricular Tachycardia (SVT) after her surgery. These conditions she had are different from what she suffers from as a result of the mesh because she did not have complaints of dyspareunia and pain with penetration prior to surgery. In fact the scarring, pelvic pain, erosion, etc. generally do not occur in the absence of mesh. It is my opinion to a reasonable degree of medical probability that the vaginal mesh erosion and dyspareunia suffered by Ms. Barner were caused by the Bard Avaulta Plus mesh implanted in her body. Based on my education, training, and experience in complicated pelvic floor reconstructive surgery, as well as my familiarity with published medical and scientific literature relating to mesh complications, I am aware that:

The four arms of the Avaulta Plus or Solo cause scarring in the tissues which is painful, restrict movement in the vagina and pelvis, cause tissue shrinkage due to scarification, do not

scar or shrink symmetrically, roll and curl which damages tissue and restricts motion; the Avaulta Plus and Solo have inadequate pore size for proper tissue ingrowth and therefore result in excessive scar plate formation; the mesh rolls, bunches and restricts the necessary natural motion in the pelvis and vagina.

As I mentioned earlier, I am familiar with the Avaulta Solo and Avaulta Plus kits specifically. I have personally removed Avaulta Plus and/or Solo mesh. Lastly, I have been to many professional conferences both with the AUGS and with the Society of Pelvic Surgeons where the Avaulta Solo and Plus were discussed.

In considering the cause of the mesh erosion and subsequent dyspareunia and vaginal scarring and discharge suffered by Ms. Barner, I first ruled in the mesh as a potential cause because her dyspareunia began a month after her surgery requiring two OR visits for revision (5/27/08, 8/15/08). During the second OR visit in 8/15/08, the surgeon noted that there was a 2 cm long/0.5 cm wide area in the anterior vaginal wall, which had exposed mesh. This was thought to be the result of a reaction to the Avaulta Plus porcine mesh coating, which resulted in a long term delayed healing after over six months of numerous treatments. She continued to have insertional dyspareunia despite vaginal estrogen therapy, followed by a 4-month treatment with vaginal dilator likely because of scar tissue from her previous surgery. She was eventually seen by a second provider on 05/18/09. At this point patient had failed conservative therapy and wanted to proceed with surgery. Although at the initial evaluation by the second provider no mesh erosion was visualized (5/18/09), during the second OR visit on 3/15/10, mesh was noted protruding from the left lateral vaginal wall which was excised.

The next step in my analysis was to rule out the other potential causes for dyspareunia such as vaginismus, inadequate lubrication, atrophy, menopause, infection and vulvodynia. It

was documented that the patient was sexually active prior to surgery and there were no issues of dyspareunia. All her symptoms and complaints started a month after her surgery. I considered each of these factors, and I concluded that they were not the cause of the dyspareunia and vaginal scarring suffered by Ms. Barner because of the sequence of events described above. Based on the foregoing analysis, and based on my education, training, experience and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of the dyspareunia and vaginal scarring suffered by Ms. Barner was the Avaulta Plus.

RELEVANT MEDICAL HISTORY – PATRICIA BOSSE

Patricia Bosse is a 48 year old G6P4024 with multiple medical problems including COPD, chronic back pain, hypothyroidism, GERD, bipolar disorder/depression, history of substance abuse currently sober, chronic pelvic pain, and endometriosis. She had a supracervical hysterectomy in 1995 for apparent uterine prolapse and pelvic pain. PB presented to her internist in 2009 with complaints of pelvic pain, prolapse and urinary stress incontinence, for which she was referred to Dr. Schulte.

Most relevant parts of the medical history, in chronological order:

11/16/09 – Note by Dr. Raymond Schulte.

> -Pt reports history of endometriosis. Complains of pain in Pfannensteil incision and pelvic pain. Has typical urinary stress incontinence (SUI) with feeling that things are slipping down when she coughs or exercises.
>
> -Exam findings: SUI with loss of UV angle, worse with cough. Apex well supported. Rectovaginal wall feels thin but it "seems substantial enough to hold up." Nodularity of uterosacrals, cul-de-sac and in Pfannensteil incision scar. External genitalia, vulva, vagina, Skenes, Bartholin's normal.

-Impression: Loss of UV angle with typical SUI and probable continuing ongoing endometriosis

-Recommendation: Laparoscopic BSO and transobturator midurethral sling.

11/30/09 – Lpsc LSO, RO, transobturator sling and posterior repair with mesh.

-Preop notes: Pt adds c/o rectal pressure, difficulty defecating, on exam 2nd-3rd degree rectocele. Risks of posterior repair with mesh discussed with pt, pt understands and accepts risks.

-Op report: Relevant findings – Pelvic support at apex was good but significant loss of support at urethrovesical angle of posterior wall. Procedure described in normal, standard fashion. No complications. Right tube with significant scarring so not removed.

- OR documents contain product stickers from Align transobturator mesh sling device and Avaulta Solo posterior mesh support system

-Benign pathology

4/5/10: Dr. Schulte: Pt with dyspareunia and tenderness at introitus. Was seen by Dr. VerMaas who noted mesh exposure at posterior fourchette. On exam at the posterior fourchette, very small segment of blue midline of posterior mesh is visible. Skin separation, this is sitting in a very small crater. Posterior wall well supported but has tenderness at level of pelvic sling muscles and vaginal girth is diminished. Impression: Small mesh exposure, fairly good chance that will heal over with Estrace cream, discussed findings with pt. Recommend also doing Kegel‟s and pelvic relaxation techniques and how to dilate to make intercourse more comfortable. Follow up in 1 month.

5/17/10: Dr. Schulte: Follow up visit. Seen 6 weeks ago, had exposed mesh just above posterior fourchette in the midline slightly to the right, started on estrogen cream. On today‟s exam - support and upper vagina normal. In lower vagina just above carunculae the pt is very tender and can feel just a small amount of mesh but was unable to spread tissue enough to see the mesh which is “distinctly improved from six weeks ago.” Plan to continue Estrace cream and follow up in two months.

3/15/12: Pt call to Dr. Schulte‟s office with c/o mesh exposure, apt made for next day.

3/16/12: Dr. Schulte: Pt c/o pain at posterior fourchette x 4 months. Not taking anything for pain. No drainage or bleeding. On exam very small mesh exposure at right posterior fourchette visualized. Mesh excised. Plan to follow up in 6 weeks.

3/19/12: Pt called office asking to see a different doctor for removal of mesh. Hung up on Dr. Schulte‟s nurse.

Per note from Dr. Leu dated 3/2014, mesh removed in office by Dr. Schulte but with continued pain and occasional bleeding, urinary frequency and urgency.

4/23/12 (Dr. Leu): Cysto- normal, exam visualized small thread of mesh extruding through posterior vaginal wall proximal to introitus about 2 cm

5/9/12 (Dr. Leu): urodynamics

6/21/12 (Dr. Leu): vaginal removal of mesh, subsequently pain improved

-Op report notes mesh resection was difficult. Findings – Some mesh fibers extruding at the introitus just to right of midline less than a centimeter in diameter. Palpable ridges of what appeared to be rolled up mesh and possible even ridges from the arms of the mesh proximally and distally which could be felt as palpable bands and pt had discomfort at this area on pre-op exam. Using careful precise and meticulous dissection doctor was able to dissect out mesh from underlying rectum. Great care taken to avoid injury to vagina or rectum. "In the end a nice piece of mesh was retrieved." Appeared to be doubled over on itself, and it was thickened in a fibrous core of connective tissue. Rectal integrity confirmed.

-Pathology: segments of synthetic mesh material of vaginal region with focal fibrosis of adjacent tissue

11/29/12 (Dr. Leu): continues to do well but with persistent urinary urgency

4/15/13 (Dr. Leu): c/o recurrent pain with intercourse, bleeding with intercourse and intermittent abdominal cramping like a UTI, no tx of UTI symptoms.

4/20/13: CT A/P - no acute findings, degenerative disease of L5-S1. Normal urinary tract.

4/24/13 (Dr. Leu): Normal cystoscopy, no mesh in urinary tract or exposure in vagina. + Tenderness to palpation where sling palpable on either side of urethra.

5/14/13 (Dr. Leu): Uncomplicated sling removal by Dr. Leu. Discharged on POD2.

11/21/13: Worked up by Dr. Redland for abd pain, did sono and HIDA scan, neg for gallbladder pathology.

1/23/14 (Dr. Leu): vaginal pain, dyspareunia, radiates to leg and back. Recommend pelvic floor PT. Pt agrees but does not get PT as cannot afford it.

3/20/14: c/o hematuria, recent BV, tx"ed with flagyl. Vaginal, perineal pain, radiates down left leg. Right back pain, nausea, subjective fevers/chills. U dip neg including neg blood. Increased pelvic floor tone. No evidence of mesh. CT urogram normal with evidence of constipation. Recommend cysto, right retrograde pyelogram, miralax, pelvic floor PT, tissue massage.

In determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

On 11/30/09 according to the operative report and OR documents with product stickers, Patricia Bosse underwent placement of Align transobturator mesh sling device and Avaulta Solo posterior mesh support system in addition to laparoscopic procedures.

Upon review of her medical records it is evident that Patricia Bosse had chronic back pain and frequent urination as well as pelvic pain and dyspareunia prior to the implantation of the Avaulta Solo and the Align mesh sling. She also suffered back pain secondary to a car accident which occurred after she had transvaginal mesh placed. Her claims that she cannot sit or stand or walk for prolonged periods of time are more likely to be due to her chronic back pain due to degenerative disc disease (seen on a CT scan) than a mesh-related complication. Based on her medical records, she also experienced urinary frequency prior to mesh placement. Additionally, the Align mesh sling would not be expected to cause urinary frequency or urgency several years after placement unless the mesh was eroding into the bladder. A normal bladder on cystoscopy rules out this possibility and so these bladder symptoms are not related to the placement of the Align sling or the Avaulta Solo.

The pelvic pain she had prior to 11/30/09 is different from what she suffers from as a result of the Avaulta Solo mesh because her previous pelvic pain was cramping and cyclic in nature and her pelvic pain after the mesh was vaginal pain. The dyspareunia she had is also

different from what she suffers from as a result of the Avaulta Solo mesh because her previous dyspareunia was described as resulting from vaginal dryness and after the mesh placement it was due to pain in the vagina where the mesh was implanted and to a decrease in the size of the introitus after mesh placement. Neither of the problems are related to the Align sling. They are related to the Avaulta Solo mesh.

The injuries suffered by Patricia Bosse from the mesh – mesh erosion, mesh scarification, pelvic pain and dyspareunia - were not the same prior to the mesh implantation because the patient did not have evidence of vaginal scarring or erosion prior to mesh placement. Her pelvic pain differed in nature and after mesh placement was due to vaginal pain and discomfort. Her dyspareunia was also a result of vaginal pain and scarring. In fact, the scarring, vaginal pain, and erosion generally do not occur in the absence of mesh. It is my opinion to a reasonable degree of medical certainty that the mesh erosion and scarification, pelvic pain, and dyspareunia suffered by Patricia Bosse were caused by the Avaulta Solo posterior mesh support system implanted in her body and not by the Align sling.

Based on my education, training, and experience in urogynecology, including familiarity with transvaginal mesh products (their placement and removal), my familiarity with published medical and scientific literature relating to mesh complications and my review of documents and depositions set out earlier in this report, I am of the opinion that:

The four arms of the Avaulta Solo cause scarring in the tissues which is painful, restricts movement in the vagina and pelvis, causes tissue shrinkage due to scarification, do not scar or shrink symmetrically, roll and curl which damages tissue and restricts motion; the Avaulta Solo has inadequate pore size for proper tissue ingrowth and therefore results in excessive scar plate

formation; and the mesh rolls, bunches and restricts the necessary natural motion in the pelvis and vagina.

In considering the cause of the mesh erosion and scarification, pelvic pain, and dyspareunia suffered by Patricia Bosse, I first ruled in the Avaulta Solo mesh as a potential cause because the symptoms of vaginal pain and painful intercourse are often present in patients with mesh erosion and exposure and scarring. Upon review of the medical records of Patricia Bosse, on several physical exams she is noted to have mesh visible in her posterior vagina which did not improve following initial treatment with estrogen cream. In the operative report of the posterior mesh removal it was noted that mesh fibers were extruding at the introitus just to right of midline less than a centimeter in diameter, there were palpable ridges of what appeared to be rolled up mesh and possibly even ridges from the arms of the mesh proximally and distally which could be felt as palpable bands. The patient had discomfort at this area on preoperative exam. Once the mesh was removed it appeared to be doubled over on itself, and it was thickened in a fibrous core of connective tissue. Following surgical resection of the mesh the pathology report demonstrated mesh with focal fibrosis of adjacent vaginal tissue.

It is also common to have bacterial infections of the exposed mesh, but Ms. Bosse had a history of infections and was a smoker. Therefore, she has other causes for her bacterial infections.

The next step in my analysis was to rule out the other potential causes, including atrophic vaginitis and endometriosis. I considered atrophic vaginitis and I concluded that it was not the cause of the pelvic pain and dyspareunia suffered by Patricia Bosse because her symptoms did not improve following a treatment course of estrogen cream. Mesh erosion was still present following treatment. Endometriosis was not the cause of her pain as she had her ovaries removed

at time of the mesh placement and her pain was not characteristic of endometriosis (which usually consists of cyclic, cramping pelvic pain).

Based on the foregoing analysis, and based on my education, training, experience and knowledge, it is my opinion to a reasonable degree of medical certainty that the cause of the mesh erosion, scarification, pelvic pain, and dyspareunia suffered by Patricia Bosse was the Avaulta Solo posterior mesh support system.

RELEVANT MEDICAL HISTORY – FAYE TINNEN

Most relevant parts of medical history in this case, in chronological order:

- Visit with Dr. Madani (12/12/07): complains of burning and itching during and after intercourse, on exam with dystrophic vulvitis, rectocele and cystocele, placed on Temovate cream
- Visit with Dr. Madani (2/27/08): f/u for vulvar dystrophy, maintained on Temovate cream
- Visit with Dr. Weiss (4/28/08): complains of vaginal pressure, on exam grade 2 rectocele and grade 1 cystocele, offered pessary but declined, interested in surgery in June-July
- Visit with Dr. Weiss (5/27/08): pre-op visit, discussed AP repair with Avaulta, risks explained (mesh erosion not mentioned in records)

Surgery 6/5/08- Dr. Michael Weiss- Ant/Post Repair with Avaulta Mesh. Procedure: Anterior/Posterior Colporrhaphy/ Posterior Avaulta/ Cystoscopy. Time in 12:51PM, Time out 2:04PM. Posterior Avaulta was used, however the type of mesh (Solo vs Plus) was not specified by surgeon or by OR staff in operative records. In the "implants" section all that is written is the word "vagina." Sticker from the product was included however (see Sticker Page), and LOT# CVRK0020 is consistent with Avaulta Plus Biosynthetic Support System.

- Visit with Dr. Weiss (6/16/08): 11 days post-op, had episode of vaginal bleeding, on exam healing well, describes some "friability along suture lines" and silver nitrate applied

- Visit with Dr. Weiss (7/16/08): 6 weeks post-op, complains of foul-smelling vaginal discharge with brownish blood on occasion, on exam no evidence of erosion

- Visit with Dr. Weiss (7/29/08): 8 weeks post-op with vaginal discharge and bleeding, on exam 0.5cm area on post vagina with separation of vaginal mucosa and small area of mesh visualized, sent home with vagifem and treatment for BV.

- Visit with Dr. Weiss (9/19/08): annual exam, exam significant for "small erosion of vaginal mesh," small area of mesh excised

- Visit with Dr. Madani (10/6/08): 1st visit with Dr. Madani, 4 months post-op, had seen Dr. Weiss several times since surgery and had pieces of mesh removed in the office and continues to have discharge, on exam clear protrusion of mesh in lower third of vagina above sphincter, about 1.5cm wide, vaginal mucosa totally separated in midline allowing mesh to protrude through, surgery offered and risks thoroughly reviewed including 30% failure rate

- Visit with Dr. Madani (12/8/08): Pre-op visit for removal of mesh, officially transferred care to Dr. Madani, risks reviewed including requiring additional surgery in the future, vaginal scarring and stenosis, dyspareunia.

Surgery 12/15/08- Dr. Behrouz Madani- Removal of posterior mesh. Pre-op Diagnosis: "chronic mesh erosion of post Avaulta through vaginal mucosa..." and "high rectocele due to failed posterior Avaulta mesh application." Pre-op findings: 1.5-2cm erosion on posterior vaginal wall cuff included, mild rectocele. Procedure: Removal of large portion of posterior Avaulta

Mesh with Posterior colpoperineorrhaphy. Time in room: 11:40AM, Time out: 12:44PM. Pathology Report: largest mesh fragment measuring 2.3cm in greatest dimension

- Visit with Dr. Madani (12/22/08): 1 week post-op visit after removal of mesh, healing well
- Visit with Dr. Madani (2/17/09): complaining of dyspareunia, on exam stenotic ring seen in mid-vagina "compartmentalizing vaginal canal into two segments"
- Visit with Dr. Madani (8/4/09): complaining of pelvic pressure, discomfort with intercourse, on exam stenotic ring in upper third of vagina seen, which barely admits two fingers, advised use of vaginal dilators for 6-8 weeks
- Visit with Dr. Madani (7/29/2010): annual exam, complaining of severe pain and discomfort with intercourse and unable to perform, found to have narrowing of mid-vagina and vulvitis, counseled regarding surgical revision, advised to continue Premarin cream and Clobetasol twice daily x 10 days
- Visit with Dr. Madani (9/28/10): Pre-op visit, risks reviewed including vaginal stenosis and dyspareunia, reviewed need for estrogen cream and use of vaginal dilators

Surgery 10/4/2010- Dr. Behrouz Madani- Revision of vaginal scar. Procedure: EUA/Revision of vaginal scar/Perineoplasty. Op Report Findings: "...vaginal canal shortened by the presence of a circular ring of scar tissues in the mid-portion of the vagina, making the vaginal penetration beyond the point literally impossible. The ring would only admit an index finger through. Half of her vagina was above the ring, but rendered nonfunctional due to inability to have penile penetration through intercourse. There was also scarring of the introitus and narrowing at the opening of vagina..." Time in: 10:57am, Time out: 11:31am.

- Visit with Dr. Madani (10/12/2010): 1 week post-op visit- healing well, 2 fingers fit loosely in vagina without pain, advised can resume sexual activity 4 weeks post-op and use vaginal dilators as needed, f/u prn

- Visit with Dr. Madani (10/5/2010): POD-1, removal of vaginal packing, advised to use vaginal dilator twice daily until vaginal tissue becomes epithelialized

- Visit with Dr. Madani (3/9/11): CC- follow-up, able to have intercourse and happy with surgical outcome, encouraged to use Premarin cream

- Visit with Dr. Madani (7/27/11): Annual exam, complains of vaginal pressure. On exam vulva and vagina appeared normal with no evidence of prolapse, some mild atrophic vaginitis noted. Cuff well suspended.

In determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Ms. Tinnen had pre-operative burning and itching during and after intercourse in December 2007. She was diagnosed with dystrophic vulvitis and was treated with topical Temovate cream, which is a steroid cream. This condition was limited to the vulva and introitus, and not to the vagina proximal to the introitus (the area where the Avaulta mesh was placed). Once the vulvitis resolved the patient complained of prolapse symptoms, specifically vaginal pressure. It was at that time that decision was made to proceed with corrective prolapse surgery, and on June 5, 2008 she underwent and anterior and posterior repair with Avaulta mesh

performed by Dr. Weiss. The vulvitis she had prior to implantation is different from the complications she suffered as a result of the Avaulta mesh because the mesh caused a structural disruption of the vagina and not on the vulva. The pain and scarring she experienced in the vagina do not occur from vulvitis and are directly related to the mesh. It is my opinion, to a reasonable degree of medical certainty, that the mesh erosion, pain, and scarring, suffered by Ms. Tinnen were caused by the Avaulta product implanted in her body. Based on my education, training, and experience in complicated pelvic floor reconstructive surgery, as well as my familiarity with published medical and scientific literature relating to mesh complications and depositions and documents that I have reviewed in the Bard litigation as stated earlier, I am aware that: The four arms of the Avaulta Plus cause scarring in the tissues which is painful, restricts movement in the vagina and pelvis, causes tissue shrinkage due to scarification, do not scar or shrink symmetrically, roll and curl which damages tissue and restricts motion. The Avaulta Plus and Solo have inadequate pore size for proper tissue ingrowth and therefore result in excessive scar plate formation, and the mesh rolls, bunches and restricts the necessary natural motion in the pelvis and vagina.

In considering the cause of the mesh erosion and subsequent dyspareunia and vaginal scarring and deformation of the vagina suffered by Ms. Tinnen, I first ruled in the mesh as a potential cause because her problems began 11 days post-op when she had vaginal bleeding and again at 6 weeks when she had malodorous discharge and then at 8 weeks when mesh erosion was apparent to the surgeon. At that time he attempted to trim the exposed mesh in the office. Once the mesh was eventually removed by a second surgeon 6 months later, scarring of vaginal canal was apparent and mentioned in the operative report. The patient then required another surgery almost 2 years later because she was unable to have sex due to the scarring that had

occurred likely from the mesh, causing vaginal stenosis and inability to accommodate more than 1 finger in the vagina. The next step in my analysis was to rule out the other potential causes, including other causes of dyspareunia such as vaginismus, vulvitis, inadequate lubrication, atrophy and vulvodynia. It was documented that the patient was sexually active prior to surgery and the patient in this case actually did suffer from "burning and itching during and after sex" and was diagnosed and treated for dystrophic vulvitis. Once this condition improved she became bothered by the "pressure" she was feeling as a result of her prolapse and that is when she became interested in surgical correction. I considered each of these factors, and I concluded that they were not the cause of the dyspareunia and vaginal scarring suffered by Ms. Tinnen because of the sequence of events described above. Based on the foregoing analysis, and based on my education, training, experience and knowledge, it is my opinion to a reasonable degree of medical certainty that the cause of the dyspareunia and vaginal scarring suffered by Ms. Tinnen was the Bard Avaulta posterior mesh.

RELEVANT MEDICAL HISTORY – PATRICIA GOLD

Most relevant parts of medical history in this case, in chronological order:

- Visit with Dr. Cappiello (5/08/08) Patient with chief complaint of vaginal vault prolapse with retention of urine. Stage 3 prolapse on exam. Referred after her primary OBGYN, Dr. Vieira tried conservative management with multiple pessaries.

- Visit with Dr. Cappiello (5/21/08): Urodynamics showed somewhat diminished capacity at 349ml, stress leak at 200ml, Urethral closure pressure 62. Noted obstruction from prolapse.

- Visit with Dr. Cappiello (6/22/08): Patient decides to proceed with surgical correction.

[Surgery 6/23/08- Dr. Cappiello- pubovaginal sling, urethrolysis, cystocele repair with mesh, rectocele repair with mesh, vaginal vault suspension, enterocele repair, perineal seal repair, cystourethroscopy, placement of graft material] Patient consented for "possibility of vaginal infection, erosion, urinary tract infection, bladder ureteral and/or rectal injury along with the possibility of mesh erosion…" Sticker shows Align and Avaulta Solo Anterior and Posterior.

- Visit with Dr. Cappiello (7/01/08): post-op, healing well, no issues. Follow up 3 months

- Visit with Dr. Cappiello (9/23/08): post-op, complains of bloody vaginal discharge on occasion, on exam evidence of erosion. Decision made to excise mesh erosion.

[Surgery 11/20/08- Dr. Cappiello- Removal of exposed anterior mesh] Anterior mesh found to be eroded. This was excised and removed. Interstitial cystitis was seen as bleeding on hydrodistention to 600ml

- Visit with Dr. Cappiello (12/04/08): post-op, patient doing well without complaints. Placed on Elmiron for interstitial cystitis.

- Visit with Dr. Goldman (3/26/09): Initial visit with chief complaint vaginal spotting and discharge. On exam a 2x1cm anterior mesh exposure was noted.

- Visit with Dr. Goldman (4/20/09): Preop H&P for anterior vaginal mesh exposure. Planned excision and vaginoscopy and cystoscopy

[Surgery 4/21/09- Dr. Goldman- Removal of 2-3cm of exposed anterior mesh] Consent for above procedure with risks of "vaginal shortening, painful intercourse, chronic vaginal wound" communicated

- Visit with Dr. Goldman (5/28/13): Patient had followed up with no issues until this date, where she complained of worsening pelvic pain, dyspareunia. A palpable cord of mesh material, which was tender, noted in the vagina. A CT to rule out mass was done and the diagnosis was likely mesh implant. A treatment course of flexeril, and pelvic physical therapy commenced in the following months.

-Visits with Foundation physical therapy (7-9/2013) Therapist worked with patient. Hypertonicity located in introits and levator ani muscles. Some functional improvement noted, but painful. Patient referred to Cleveland Clinic Florida for further surgical management as the patient desired.

-Visit with Dr. Davila (11/26/13): Pain at the arms of the mesh on exam. Pain localized to mesh arms L>R. Patient opts for surgery over conservative option of vaginal estrogen.

[Surgery 1/20/14- Dr. Davila- Removal of firm contracted posterior arms of mesh. Anterior mesh with arms left in place since asymptomatic]

- Visit with Dr. Goldman (3/20/14): Patient doing well with improved pain post operatively

In determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology,

and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Ms. Gold had pelvic pain and during her second surgery to revise the mesh erosion, it was noted that she had signs of interstitial cystitis on cystoscopy. Interstitial cystitis is an inflammatory condition of the bladder, which often leads to pelvic pain, urgency, frequency, and dysuria. The pain and scarring she experienced in the vagina did not occur from interstitial cystitis and are directly related to the mesh. It is my opinion to a reasonable degree of medical certainty, that the mesh erosion, pain, and scarring, suffered by Ms. Gold were caused by the Avaulta Solo product implanted in her body. Based on my education, training, and experience in complicated pelvic floor reconstructive surgery, as well as my familiarity with published medical and scientific literature relating to mesh complications, I am aware that:

The four arms of the Avaulta Solo cause scarring in the tissues which is painful, restricts movement in the vagina and pelvis, causes tissue shrinkage due to scarification, do not scar or shrink symmetrically, roll and curl which damages tissue and restricts motion; the Avaulta Plus and Solo have inadequate pore size for proper tissue ingrowth and therefore result in excessive scar plate formation; the mesh rolls, bunches and restricts the necessary natural motion in the pelvis and vagina.

In considering the cause of the mesh erosion and subsequent dyspareunia and vaginal scarring and deformation of the vagina suffered by Ms. Gold, I first ruled in the mesh as a potential cause because her problems began at her 3 month follow up when mesh erosion was apparent to the surgeon and she was suffering from bloody vaginal discharge. The following month an attempt to trim the exposed mesh in the office was deferred to the operating room,

given the size of the defect. Once the mesh was eventually removed, inflammation with scarring was apparent in the pathologist report of the dissected mesh segment. The patient subsequently required another surgery that following Spring on the anterior mesh, then again, almost 6 years later, on the posterior mesh because she was having pelvic pain during exercise and sex. This was due to the scarring that had occurred likely from the mesh causing taught tender bands of vaginal tissue. A CT scan at the time showed no pelvic masses that could account for the bands.

The next step in my analysis was to rule out the other potential causes, including other causes of dyspareunia such as vaginismus, vulvitis, inadequate lubrication, atrophy and vulvodynia. It was documented that the patient was sexually active prior to surgery and that, during her exam prior to the last mesh revision surgery, she could barely tolerate a probe into the vagina due to the painful bands and scarring. I considered each of these factors, and I concluded that they were not the cause of the dyspareunia, erosion, vaginal deformation, and vaginal scarring suffered by Ms. Gold because of the sequence of events described above.

Based on the foregoing analysis, and based on my education, training, experience and knowledge, it is my opinion to a reasonable degree of medical certainty that the cause of the dyspareunia and vaginal scarring suffered by Ms. Gold was the Bard Avaulta Solo mesh.

III. DATA CONSIDERED IN FORMING MY OPINIONS

I considered the documents identified in the footnotes of this report, as well as those listed in Exhibit B attached hereto.

IV. EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF MY OPINIONS

I may use documents that I reviewed and which are identified above, female pelvic floor models and illustrations, samples of the Avaulta Plus and Solo kits, and summaries of literature that I may prepare.

V. COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

I charge $1000 per hour for review and study of records. I charge a 50% premium on records that must be reviewed within 30 days.

Deposition and trial testimony is charged at $6,000/half day and $10,000/full day. Any work done in an 8 hour period is not billed with travel expenses. Outside of the 8 hours, travel time is billed at $250/hour.

VI. OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

9/26/14- Idupuganti, deposition as explanting surgeon

2013- Miklos, deposition and trial testimony as defense witness. (Ga.)

2011 – McCarthy v. Karounas (Pa.) – trial testimony

ALAN GARELY, M.D.

CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2014, I served the **PLAINTIFFS' RULE 26(a)(2)(B) EXPERT REPORT OF ALAN GARELY, M.D.** on the following counsel of record by electronic mail:

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